	STATE OF MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  POLICY AND PROCEDURE MANUAL <i>POLICY AND PROCEDURE</i>	CHAPTER
		Public Health
		NUMBER
		11.4
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#### A. PURPOSE

The purpose of this policy is to provide the Department of Community Health (DCH) with guidelines for utilization of residual newborn screening dried blood spots (DBS) in health research.

#### B. REVISION HISTORY

None

#### C. DEFINITIONS

**Community Values Advisory Board (CVAB)** means a board of representatives from community based and state advocacy organizations established and appointed by the Director to provide input to the Department on: 1) policies that govern the ways in which bloodspots will be acquired and used for research; 2) the governance structure of the BioTrust, including a meaningful role for the CVAB in ongoing BioTrust operations; and 3) strategies and methods to assure ongoing community awareness and engagement for informing development, review, and revision of BioTrust policies.

**Dried Blood Spot (DBS)** means the blood specimen collected from the heel of a newborn for screening for hereditary disorders, as required by the Michigan Public Health Code, Act 368 of 1978, MCL 333.5431.

**DBS Program Representative** means: State Registrar, Director of the Bureau of Laboratories and Director of the Bureau of Epidemiology or designee.

**DCH IRB** means DCH's Institutional Review Board established under DCH's Federal Wide Assurance to review all human subjects' research that is sponsored by, or involves DCH.

**Identifying information** means information that is identifiable or potentially identifiable to an individual.

**IRB approval** means approval of research by DCH's IRB.

**Material Transfer Agreement** means a contract governing the transfer of tangible research materials between two organizations and the recipient's intentions are for use in research purposes. The DCH has adopted the definitions, terms, and conditions of the Uniform Biological Material Transfer Agreement ("UMBTA") published in the Federal Register, vol. 60, March 8, 1995, page 12771 et seq. with the following exception. MDCH has added additional terms and conditions that apply only to the transfer of newborn screening specimens for research.

**Michigan BioTrust for Health** means the initiative by the DCH to make extra DBS from newborn screening more available for medical and public health research by storing these DBS in optimal conditions and promoting their availability to researchers.

**BioTrust Scientific Advisory Board** means a board of scientists established consistent with the requirements of Ad. Rule 325.9055 and appointed by the Director for participation on scientific advisory panels that review proposed research covered by this policy for scientific merit.

**BioTrust Scientific Review Panel** means a panel of at least three members selected from the BioTrust Scientific Advisory Board to review a specific research proposal.



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**D. POLICY**

It is the policy of the DCH to allow use of DBS in health research after a research proposal is evaluated for scientific rigor; innovation and significance to medical and public health research; human subjects' protections; and ethical standards as outlined in the procedures below, based on the guiding principles set forth by the Community Values Advisory Board.

**E. PROCEDURE**

<b><i>Responsibility</i></b>	<b><i>Action</i></b>
Promoting the Public's Health	<ul style="list-style-type: none"> <li>Research priorities may include but are not limited to: (1) prenatal, childhood or adult-onset disorders, and (2) environmental exposures.</li> <li>Utilization of residual DBS is not approved for research pertaining to: (1) chemical, biological or nuclear warfare, (2) cosmetics, or (3) other non-health related ventures unless for purposes related to injury or medical conditions.</li> <li>Research priorities and restrictions will be re-assessed by the Michigan BioTrust Community Values Advisory Board (CVAB) annually and upon request as technological and scientific advances occur.</li> </ul>
Establishing Review and Approval Process	<p>DBS specimens shall only be released to a researcher following review and approval by the BioTrust Scientific Advisory Board, and the DCH IRB; and completion of a material transfer agreement.</p> <ul style="list-style-type: none"> <li>Members of a <u>Review Panel</u>, from the BioTrust Scientific Advisory Board shall independently review each research protocol requesting utilization of DBS. Panel members are responsible for evaluating the study for scientific rigor, innovation and significance to medical and public health research, feasibility and consistency with the BioTrust Guiding Principles.</li> <li>The <u>DCH IRB</u>, comprised of representatives from its various programs and members from the community, shall evaluate proposals to use DBS for research to assure compliance with the US regulations that govern human subject's research (45 CFR 46) and adherence to the ethical principles of the Belmont Report<sup>1</sup>. In addition the IRB will rely on guidance from the Department's Scientific Advisory Board evaluation of the scientific merit and the CVAB advice on acceptable areas of research, to evaluate the potential benefit of the research in relation to any risk.</li> </ul>
Protecting Confidentiality	Specimens from the BioTrust and any related data may be used for research only if they cannot be manipulated by the researcher to identify an individual, unless specific informed consent is obtained or the DCH IRB issues a waiver.

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	<ul style="list-style-type: none"> <li>Following completion of newborn screening, DBS specimens shall be de-identified, coded with a unique number and retained in a secure storage facility. DCH serves as the honest broker and maintains the sole link that would enable re-coding to identify a sample. The storage code does not contain nor is it derived from directly identifiable information, i.e. social security number, birth date, etc. DBS specimens released to researchers shall be coded with a different unique number that does not contain any directly identifiable information. Any accompanying data shall only be released to a researcher after de-identification. Directly identifiable information, i.e. name or address, shall only be released to researchers when specific informed consent is obtained or the DCH IRB (in rare cases) issues a waiver.</li> </ul>
Providing Information to the Public	Scientists shall provide DCH, within one year of research completion (cessation of data analysis) or no later than the acceptance for publication, whichever comes first, a summary of the research results in aggregate form so that they can be made available to the public on a website and as required through procedures established under the Freedom of Information Act (FOIA). Upon request from the scientist, 1-year deadline may be extended by DCH for good cause. DCH will be given citation(s) for all published work utilizing the newborn screening specimens.
Reserving a Dried Blood Spot in Trust for the Parent or Child	The DCH Bureau of Laboratories shall maintain a portion of every individual's DBS sample for uses that could directly benefit the child or the child's parent or legal representative; and not allow that portion of the sample to be utilized for any research purposes through the BioTrust. Requests for such use shall be submitted in writing by the child's parent or legal representative, by the child upon reaching the age of 18 years, or by the adult child's legal representative.
Seeking Public Input	DCH shall establish mechanisms to regularly seek input from the public and key stakeholders within the community on the research direction and priorities of the BioTrust that may modify the guiding principles that serve as a basis for this policy.

#### **F. REFERENCES**

Michigan Public Health Code, Act 368 of 1978, MCL 333.2611, 333.2619, 333.5431, 333.5717, 333.5721, 333.9207, 333.9227.  
Michigan Administrative Code, R 325.167; R 325.9055; R 325.9075.  
DCH Policy and Procedure 6.18 (Institutional Review Board)  
DCH Policy and Procedure 11.1 (Newborn Screening Specimens)  
National Institutes of Health. <http://ohsr.od.nih.gov/guidelines/index.html>



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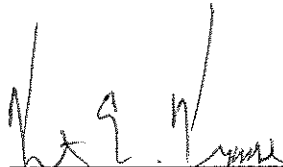
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**G. CONTACT**

For additional information concerning this policy, contact the Genomics and Genetic Disorders Section at 517-335-8887.

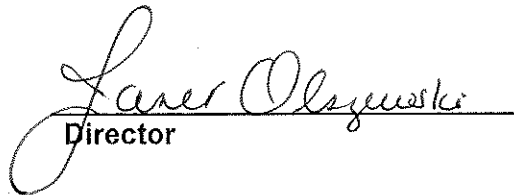
RECOMMENDED BY:

  
Deputy Director

DATE:

11/10/10

APPROVED BY:

  
Director

DATE:

11/11/10